

Remarks

A. Pending Claims

Claims 15-38 are pending. Claims 35-38 are new.

B. The Claims Are Not Anticipated by Sertich Pursuant To 35 U.S.C. §102(b)

Claims 15-18, 21-24, 27-31, and 33 were rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 5,800,550 to Sertich (hereinafter “Sertich”). Applicant respectfully disagrees with these rejections.

The standard for “anticipation” is one of fairly strict identity. A claim can only be anticipated if each and every element set forth in the claims is found to be either expressly or inherently described in the cited art. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 728, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), MPEP 2143.03.

Claim 15 describes a combination of features, including but not limited to the features of “an insert comprising a support surface for the second vertebra, the support surface configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra”. Sertich does not appear to teach or suggest at least the above-quoted feature of claim 15 in combination with the other features of the claim.

As noted in the Office Action, “Sertich discloses the following: an intervertebral implant for a human spine, comprising: a cage element (30) with an opening (44), superior surface (32)

and an inferior surface (34) that inhibits movement between the two vertebra; an insert (70) comprising an inferior surface (74), and a support surface (72) ...”

The portion of the Sertich device that is cited as corresponding to the insert of claim 15 is an “anchoring peg 70” (see column 6, line 10). The anchoring peg does not include at least the claimed feature of “a support surface for the second vertebra configured to inhibit movement of the second vertebra towards the first vertebra” in combination with the other features of the claims. As depicted in FIG. 2 and FIG. 9 of Sertich, the insert does not support the vertebra above cage element (30). The anchoring pegs of Sertich are not supports but inhibit lateral and or rotation of the implant. Sertich teaches that the cage element (30) is the support for the vertebrae.

The Office Action states that the insert of Sertich includes “a support surface (72)”. Support surface 72 is positioned in cage element 30 of Sertich and IS NOT “a support surface for the second vertebra” as called for in claim 15.

In addition, the shape of the anchoring pegs of Sertich facilitate insertion into the vertebra (which is not inhibiting movement of the second vertebra toward the first vertebra). For example, column 6, lines 18-21 of Sertich states “More specifically, the anchoring pegs 70 provide a serrated edge which offers less resistance to penetration into the vertebral bone than a solid edge would.” As noted above, Sertich supports the second vertebra on the cage element (30).

The above-quoted feature of claim 15 includes recitation in the claim of sufficient structure to warrant the presence of the functional language. The above-quoted feature includes “an insert comprising a support surface for the second vertebra”. The inclusion of the “support surface for the second vertebra” provides sufficient structure for the subsequent feature of “configured to inhibit movement of the second vertebra towards the first vertebra”. Applicant submits that the above-quoted feature of claim 15 should be given patentable weight.

Sertich does not appear to teach or suggest at least the feature of “an insert comprising a support surface for the second vertebra configured support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra, wherein the insert is configured to be positioned at least partially in the cage element” in combination with the other features of the claim. Applicant requests removal of the anticipation rejection of claim 15 and the claims dependent thereon.

Claim 21 describes a combination of features including, but not limited to, the features of “an insert comprising an inferior surface and a support surface for the second vertebra, the support surface configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra”. Sertich does not appear to teach or suggest at least the above-quoted features of claim 21 in combination with the other features of the claim.

The insert of Sertich does not teach or suggest each and every element set forth in the claim. The portion of the Sertich device that is cited as corresponding to the insert of claim 21 is an “anchoring peg 70” (see column 6, line 10). The anchoring peg does not include at least the claimed feature of “a support surface for the second vertebra configured to support the second vertebra above the superior surface of the cage element”. As depicted in FIG. 2 and FIG. 9 of Sertich, the insert does not support the vertebra above cage element (30). The anchoring pegs of Sertich are not supports but inhibit lateral and or rotation of the implant. Sertich teaches that the cage element (30) is the support for the vertebrae.

The Office Action states that the insert of Sertich includes “a support surface (72)”. Support surface 72 is positioned in cage element 30 of Sertich and IS NOT “a support surface for the second vertebra” as called for in claim 21.

In addition, the shape of the anchoring pegs of Sertich facilitate insertion into the vertebra (which is not “inhibiting movement of the second vertebra toward the first vertebra”). For example, column 6, lines 18-21 of Sertich states “More specifically, the anchoring pegs 70 provide a serrated edge which offers less resistance to penetration into the vertebral bone than a

solid edge would.” As noted above, Sertich supports the second vertebra on the cage element (30).

The above-quoted feature of claim 21 includes recitation in the claim of sufficient structure to warrant the presence of the functional language. The above-quoted feature includes “an insert comprising a support surface for the second vertebra”. The inclusion of the “support surface” provides sufficient structure for the subsequent feature of “configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra”. Applicant submits that the above-quoted feature of claim 21 should be given patentable weight.

Sertich does not appear to teach or suggest at least the features of “an insert comprising an inferior surface and a support surface for the second vertebra configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra” in combination with the other features of the claim. Applicant requests removal of the anticipation rejection of claim 21 and the claims dependent thereon.

Claim 27 describes a combination of features including, but not limited to, the features of “an expansion member configured to be inserted in a third opening in the cage element to raise a support surface of the first insert relative to the inferior surface of the cage element, wherein the support surface of the first insert is configured to couple to a first vertebra to support the vertebra away from the cage element and inhibit movement of the first vertebra towards a second vertebra”. Claim 27 also describes the features of “wherein the expansion member when inserted in the third opening is configured to raise a support surface of the second insert relative to the superior surface of the cage element, wherein the support surface of the second insert is configured to couple to the second vertebra to support the second vertebra away from the cage element and inhibit movement of the second vertebra towards the first vertebra.” Sertich does not appear to teach or suggest at least the above-quoted features of claim 27 in combination with the other features of the claim.

In the Office Action, it is unclear if the support surface of the first insert referred to in the claim corresponds to support surface 72 of anchoring peg 70 or inferior surface 74 of anchoring peg 70 in Sertich. In the Office Action, it is unclear if the support surface of the second insert referred to in the claim corresponds to support surface 72 of anchoring peg 70 or inferior surface 74 of anchoring peg in Sertich. In any case, Sertich does not include all of the features of claim 27 as detailed below.

If the support surface of the first insert referred to in claim 27 corresponds in Sertich to support surface 72 of anchoring peg 70, then Sertich does not teach or suggest all of the features of the claim. The expansion member of the Sertich device appears to be configured to make support surface 72 of the first anchoring peg 70 approach the inferior surface 34 of the cage element 30. The support surface of the first anchoring peg (insert) would not be raised relative to the inferior surface as required in claim 27.

If the support surface of the first insert referred to in claim 27 corresponds in Sertich to inferior surface 74 (as identified in the Office Action), then Sertich does not teach or suggest all of the features of the claim. Inferior surface 74 is not a “support surface” as called for in claim 27. Identifying the first insert as including a “support surface” provides sufficient structure to support the subsequent functional language of “wherein the support surface of the first insert is configured to couple to a first vertebra to inhibit movement of the first vertebra towards a second vertebra”. The expansion member of the Sertich device does not teach or suggest at least the feature of “wherein the support surface of the first insert is configured to couple to a first vertebra to inhibit movement of the first vertebra towards a second vertebra”. As described in column 6, lines 19-21, “the anchoring pegs 70 provide a serrated edge which offers less resistance to penetration into the vertebral bone than a solid edge would.” The Sertich device is configured to facilitate movement of the first vertebra relative to the second vertebra before movement is stopped by the first vertebra contacting the inferior surface of the cage element (not the “support surface of the first insert” as in claim 27).

If the support surface of the second insert referred to in claim 27 corresponds in Sertich to support surface 72 of anchoring peg 70, then Sertich does not teach or suggest all of the features

of the claim. The expansion member of the Sertich device appears to be configured to make support surface 72 of the second anchoring peg 70 approach the superior surface 32 of the cage element 30. The support surface of the second anchoring peg (insert) would not be raised relative to the inferior surface as required in claim 27.

If the support surface of the second insert referred to in claim 27 corresponds in Sertich to inferior surface 74 (as identified in the Office Action), then Sertich does not teach or suggest all of the features of the claim. Inferior surface 74 is not a “support surface” as called for in claim 27. Identifying the second insert as including a “support surface” provides sufficient structure to support the subsequent functional language of “configured to couple to the second vertebra to inhibit movement of the second vertebra towards the first vertebra”. The expansion member of the Sertich device does not teach or suggest at least the feature of “wherein the support surface of the second insert is configured to couple to the second vertebra to inhibit movement of the second vertebra towards the first vertebra”. As described in column 6, lines 19-21, “the anchoring pegs 70 provide a serrated edge which offers less resistance to penetration into the vertebral bone than a solid edge would.” The Sertich device is configured to facilitate movement of the second vertebra relative to the first vertebra before movement is stopped by the second vertebra contacting the superior surface of the cage element (not the “support surface of the second insert” as in claim 27).

Sertich does not appear to teach or suggest at least the above-quoted features of claim 27 in combination with the other features of the claim. Applicant requests removal of the rejection of claim 27 and the claims dependent thereon.

Claim 18 and claim 24 each describe a combination of features including the feature of “wherein the support surface of the insert comprises osteoconductive mesh structure.” Claim 30 describes a combination of features including “wherein the support surface of the first insert comprises osteoconductive mesh structure.” Claim 31 describes a combination of features including “wherein the support surface of the second insert comprises osteoconductive mesh structure.” Claims 18, 24, 30 and 31 were rejected in light of column 4, lines 17-21 of Sertich which state: “Yet an additional advantage of the present invention is the provision of an

insertion tool which can be removed providing an interbody fusion cage which has hollow areas that can be packed with autologous cancellous bone or other material to promote bone ingrowth and fusion.” The quoted passage of Sertich refers to the cage element 30. The claims 18 and 24 describe “the support surface of the insert” and claims 30 and 31 describe “the support surface of the” first or second “insert”. The support surfaces are not the same as the cage element of Sertich. The Office Action implies that the corresponding structure of Sertich to the insert of the present claims is the anchoring pegs 70 of Sertich. Column 6, lines 28 and 29 state “Preferably the pegs are made of a suitable conventional metal such as the metals mentioned previously with regard to the body 30.” There is no teaching or suggestion of the above-quoted feature of claims 18, 24, 30 and 31, in combination with the other features of the claim by Sertich. Applicant requests the removal of the anticipation rejection of claims 18, 24, 30 and 31.

C. The Claims Are Not Obvious Over Sertich In View of Larsen et al. Pursuant To 35 U.S.C. §103(a)

Claims 19, 25, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sertich in view of U.S. Patent No. 5,782,832 to Larsen et al. (hereinafter “Larsen”). Applicant respectfully disagrees with this rejection.

To reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 USPQ 173, 177-178 (C.C.P.A. 1967). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP §2143.03.

As discussed above in Section B, Sertich does not teach or suggest all features of the independent claims from which claims 19, 25, and 32 depend. Larsen in combination with Sertich does not teach or suggest all of the features of claims 19, 25, and 32, as discussed in Section B.

In addition, the proposed modification of combining Larson with Sertich would change

the principle of operation of Sertich. Sertich teaches the use of an insertion tool to raise anchoring pegs. After the anchoring pegs are raised, the insertion tool is removed (the implant with removed insertion tool is shown in FIG. 2). The insertion tool must be removed. Larson depicts an insertion tool comprising a screw and cam with a portion of the screw that engages a threaded opening in the body of the cage element. The insertion tool remains in the cage element after insertion. Leaving the insertion tool in the cage element as per Larson changes the principal of operation of Sertich where the insertion tool is removed. Therefore, the teaching of the references is not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959), MPEP 2143.01VI.

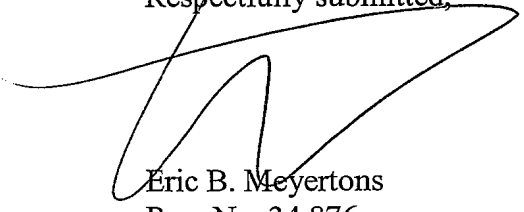
Applicant requests removal of the obviousness rejections of claims 19, 25, and 32.

D. Additional Comments

Applicant submits that all claims are in condition for allowance. Favorable consideration is respectfully requested.

Authorization for an extension of time, excess claims fees, and the fee for a Request For Continued Examination will be made upon electronic submission of this document. If any other fees are required, please appropriately charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5943-00300/EBM.

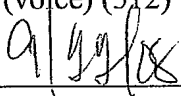
Respectfully submitted,



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